

AUG 20 2008

**5. 510(k) Summary****Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination**Device description

The Gentian cystatin C Immunoassay is a particle enhanced turbidimetric immunoassay (PETIA). The immunoparticles are made from activated polystyrene microspheres to which avian anti-human cystatin C antibodies are covalently attached. The immunoparticles and cystatin C form aggregations that change the absorbance signal, depending on the amount of cystatin C present. Measurements obtained by this device are used for the determination of Cystatin C in human serum and plasma. The Gentian cystatin C assay is calibrated with human Cystatin C calibrators. Cystatin C controls are assayed for the verification of the accuracy and precision of the Gentian cystatin C immunoassay.

Substantial Equivalence

The Gentian Cystatin C Immunoassay for the Beckman Coulter™ Synchron® and UniCel® Systems is substantially equivalent to the Gentian Cystatin C Immunoassay on the Abbott Architect® c8000 instrument (K071388), with respect to indications for use, device design and material. The difference between the Synchron and UniCel applications and the FDA cleared Architect application is a minor difference in the instruments' methods in curve fit for calibration curve establishment. In the Architect a spline method is used while in Synchron and UniCel a math model 8 is used (described in instrument manual). The Gentian assay is a particle enhanced turbidimetric immunoassay (PETIA), and can be used on all commercially available automated clinical chemistry analyzers using a light absorption detection system. The Gentian device uses avian antibodies and it is known by one skilled in the art that there is no interaction between Rheumatoid Factor (RF) and avian antibodies.

Comparison to predicate device

The substantial equivalence, safety and efficacy of the Gentian cystatin C Immunoassay on Architect versus Synchron and UniCel was evaluated in a comparison study between the Architect and Synchron instruments. The aim was to demonstrate substantial equivalence between the instrument applications of the Gentian Cystatin C Immunoassay. A summary of the method comparison regression analyses results are shown in table 1.

**Table 1.** Summary of comparison regression analysis between Synchron and Architect

<b>Sample type</b>	<b>Regression parameter</b>	<b>Acceptance criteria</b>	<b>Coefficient</b>	<b>Confidence Interval</b>
Serum N=47	Slope	$1.0 \pm 0.075$	0.95	0.93 - 0.97
	Intercept (mg/L)	$0 \pm 0.20$	0.17	0.13 - 0.22

The agreement between the Beckman Coulter's Synchron and UniCel Systems was further evaluated by an instrument variation study between the two applications. A summary of the method comparison regression and bias analyses results are shown in table 2.

**Table 2.** Summary results from instrument variation regression and bias analysis of Synchron LX20 vs UniCel DxC.

Analysis	Parameter	Acceptance criteria	Coefficient	Confidence Interval
<b>Passing-Bablok N=50</b>	Slope	$1 \pm 0.05$	0.97	0.95-1.00
	Intercept (mg/L)	$0 \pm 0.10$	0.03	-0.01-0.06
<b>Bland-Altman N=50</b>	Bias (%)	$0 \pm 5$	-1.2	-2.4-0.0
	95% limit of agreement (%)	$0 \pm 10$	-9.5 to 7.1	-11.6 - -7.4 5.0 - 9.2

#### Performance characteristics

The measuring range is 0.4-8.0 mg/L. The reference range is 0.62-1.15 mg/L. Linearity is absolute over the whole assay range. Total imprecision CV, measured over 3 days for Synchron is in the range 2.2 – 5.4 %, and measured over 5 days for UniCel is in the range 2.9 – 5.8 %. Interference studies show no significant interference, from hemoglobin (400 mg/dL), intralipid (1200 mg/dL), triglycerides (15 mmol/mL) and bilirubin (20 mg/dL). Due to the use of avian antibodies, no interference with rheumatoid factor is detected. No carry-over is detected. The limit of detection (LoD) is below 0.35 mg/L and the limit of quantification (LoQ) (within CV 7%) are below 0.47 mg/L for both Synchron and UniCel applications, which is below the lowest calibrator concentration. Sample stability is up to one month at 2-8°C. Stability of the reagents at 2-8°C is calculated to be at least 24 months. Stability of the reagents in use is minimum 4 weeks. Recovery is 94-107 %. It is estimated that there is no Antigen hook effect in cystatin C samples below 25 mg/L, in addition the Synchron and UniCel instruments are programmed to not report any results above the highest calibrator. The sample matrix equivalence study showed that serum and EDTA/LiHeparin plasma give identical cystatin C results. Method comparison to another commercially available Cystatin C method showed a very good agreement.

#### Conclusion

When considering the comparison study between the Gentian Cystatin C Immunoassay on Architect and Synchron, and the instrument variation study between Synchron and UniCel, and the additional documentation supporting the Gentian Cystatin C Immunoassay on Synchron and UniCel Systems, it can be concluded that the Gentian Cystatin C Immunoassay when measured on the Beckman Coulter™ Synchron® and UniCel® Systems is as safe and effective as, and substantially equivalent to the Gentian Cystatin C Immunoassay when measured on the FDA cleared Abbott Architect c8000 analyzer.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
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**AUG 20 2008**

Gentian AS  
R & R Registrations  
c/o Dr. Eric S. Gruff  
9915 Cam. Chirimolla  
San Diego, CA 92131

Re: k081875  
Trade/Device Name: Gentian Cystatin C Immunoassay  
Regulation Number: 21 CFR §862.1225  
Regulation Name: Creatinine Test System.  
Regulatory Class: Class II  
Product Code: NDY  
Dated: July 24, 2008  
Received: July 25, 2008

Dear Dr. Gruff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

## Indication for Use

510(k) Number (if known): K081875

Device Name: Gentian Cystatin C Immunoassay

### Indication For Use:

Gentian Cystatin C Immunoassay is an *in-vitro* diagnostic test for quantitative determination of cystatin c in human serum and plasma. The measurement of cystatin c is used in the diagnosis and treatment of renal diseases.

The instruments that can be used with the assay are:  
The Beckman Coulter™ Synchron® and UniCel® Systems

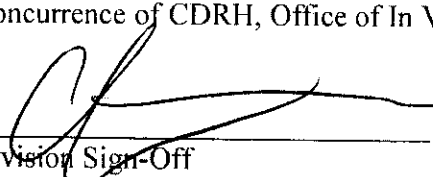
Prescription Use   X    
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use         
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

  
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Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k)   K081875